Heparin (100UI/kg) was given at the beginning of the procedure. All the procedures were done under general anesthesia, and simultaneous Transesophageal Echocardiography. QP/QS were measured in all pt. with Ostium Secundum or Multifenestrated ASD. All pr. included in this study had significant left to right shunt (>2/1).

Deliver Sheath: 9-14fr.

Patients with PFO have had history of TIA or STROKE without any concomitant disease that justified this event.

Complete closure of the defect was achieved in the vast majority of patients at 24 hrs.

The ULTRASEPT device is the last generation of CARDIA ASD closure devices. It has a double round disc design made of nitinol, covered with polyvinyl alcohol. It’s a self-centering device, able to close ASD defects between 6-38mm. Outside diameter disc is 14mm larger than centering diameter (7mm per side).

Deliver Sheath: 9-14fr.

All the procedures were done under general anesthesia, and simultaneous Transesophageal Echocardiography. Vascular access was femoral vein in all pt.

Heparin (100UI/kg) was given at the beginning of the procedure. QP/QS were measured in all pt. with Ostium Secundum or Multifenestrated ASD. All pr. included in this study had significant left to right shunt (>2/1).

Balloon sizing with “stop flow” technique was done on pt. with Ostium Secundum defects. In those pr. with a Patent Foramen Ovale (PFO) or a multifenestrated ASD, it wasn’t done.

During the quoted period, were submitted to the procedure 43 pt.

In the study it was assessed: Effectiveness of the implantation procedure and the occurrence of complications related to the procedure or the prosthesis used, and the persistence of residual shunt.

RESULTS

Succesful implant 39 patients (93%).

Non effective procedure in 3 patients (6.9%): 1pt. (2.3%) the ASD couldn't be excluded due to insufficient posteroinferior rim. 1pt. (2.3%) had a tear in the interatrial septum during procedure (fig.7), with unstable position of the device and significant residual shunt. The device was recaptured with a snare and the pt. sent to a programmed surgery.

One pt. had 2 ASD distant from each other. It was occluded the one with the biggest diameter and was left a 3 mm. defect without hemodynamic repercussion in the follow-up (FU).

Complications: in 1pt. the device embolized at 24 hrs, and was sent to surgery to retrieve the device and ASD closure, without complications.

During the follow up, were evaluated: the occurrence of complications related to the procedure or the prosthesis used, and the persistence of residual shunt.

Succesful implant 39 patients (93%).

Non effective procedure in 3 patients (6.9%): 1pt. (2.3%) the ASD couldn't be excluded due to insufficient posteroinferior rim.

Effectiveness

In 1pt. the device embolized at 24 hrs, and was sent to surgery to retrieve the device and ASD closure, without complications.

Effectiveness: successful implant 39 patients (93%).

Complications: in 1pt. the device embolized at 24 hrs, and was sent to surgery to retrieve the device and ASD closure, without complications.

RESULTS

Succesful implant 39 patients (93%).

Non effective procedure in 3 patients (6.9%): 1pt. (2.3%) the ASD couldn’t be excluded due to insufficient posteroinferior rim. 1pt. (2.3%) had a tear in the interatrial septum during procedure (fig.7), with unstable position of the device and significant residual shunt. The device was recaptured with a snare and the pt. sent to a programmed surgery.

One pt. had 2 ASD distant from each other. It was occluded the one with the biggest diameter and was left a 3 mm. defect without hemodynamic repercussion in the follow-up (FU).

Residual shunt: Transthoracic echo was done at 24hs, (1month, 3month and 6 month after procedure 97.6% (42pt) of the patient presented complete exclusion at 24hs control.

1pt presented residual shunt after procedure during follow up. It has 2 ASD distant each other. During the procedure it was closed the bigger defect, and the smaller remained patent without significant shunt.

There weren’t mortality or significant complications as major bleeding, embolization hematoma or vascular injury at the vein access. We haven’t found fracture or an injury due to erosion during the short and medium term follow up.

CONCLUSION

ASD closure with ULTRASEPT was safe, effective and well tolerated procedure, with very small number of major complication in our small series of patients.

Complete closure of the defect was achieved in the vast majority of patients at 24 hrs.